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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,459	10/02/2001	Fernando DiCaprio	S63.2-10083	9616

490 7590 09/11/2003

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/11/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,459

Applicant(s)

DICAPRIO ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6 and 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of species II (claims 1-3 and 6-15 readable thereon) in Paper No. 10 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicants fail to indicate an election of subspecies. During a telephone conversation with Mr. Richard A. Arrett on 9/4/2003 a provisional election was made without traverse to prosecute the invention of Species II, subspecies I (claims 1-3, 6, 9-15 readable thereon). Affirmation of this election must be made by applicant in replying to this Office action. Claims 4, 5 and 7, 8 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 6 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanson (6,607,552).

In regard to claim 1, Hanson disclose a stent delivery system (fig. 8) including a catheter, a stent (32), at least one sleeve (10), and at least one membrane (33).

In regard to claims 2-3, Hanson disclose a stent delivery system (fig. 6) including catheter, a stent (32), two sleeves (10) and at least one membrane (33) disposed about at least a portion of the stent positioned between the sleeves (10). Note: "disposed about" does not mean disposed directly on the surface of the stent.

In regard to claim 6, the membrane (33) constructed and arranged to be retracted off of the stent (figs. 8-9).

In regard to claim 13, the thickness of the membrane (33) is less than the thickness of the sleeve (10, figure 8).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 9-11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shull et al. (6,143,022) in view of Hanson '552. Shull et al. disclose a stent (9) may be made from self expanding material (col. 8, lines 48-50) and a membrane (20) disposed about the stent wherein the membrane is made from PTFE or polyurethane and has a thickness between .001 and .003 inches (col. 6, lines 44-55). Although, Shull et al. fail to disclose a catheter having sleeves for delivering the stent, attention is directed to the Hanson reference which discloses a stent delivering system including sleeves for securing and maintaining a reduced diameter of self expanding stent on a balloon (figs. 3-4) for delivering to a deployment site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a delivering system having sleeves for delivering the self-expanding stent of Shull et al. in order to secure the stent to a delivery catheter and maintain its reduced diameter configuration during delivery of the stent.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (6,379,382) in view of Hanson '552. Yang discloses a self-expanding stent (102, col. 5, lines 1-41) and a membrane (104) disposed about the stent wherein the membrane is a drug delivery device. Although, Yang does not disclose a catheter having sleeves for delivering the stent, attention is directed to the Hanson reference which discloses a stent delivering system including sleeves for securing and maintaining a reduced diameter of self expanding stent on a balloon (figs. 3-4) for delivering to a deployment site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a delivering system having sleeves for

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delivering the self-expanding stent of Yang in order to secure the stent to a delivery catheter and maintain its reduced diameter configuration during delivery of the stent.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731
September 8, 2003